REMARKS

Favorable consideration and allowance are respectfully requested for currently pending claims 1-28 in view of the foregoing amendments and following remarks.

Claim 29 is added. Support for this change may be found in the specification as originally filed, for instance, at Example 4.

Applicants appreciate Examiner Tram's agreement to meet with Applicants' representative on May 19, 2009 to discuss outstanding issues, and look forward to working with her.

Claims 27 and 28 stand rejected under 35 U.S.C. § 112, first paragraph, because while the specification is enabling for an oral dosage form of tramadol and diclofenac, The Office argues that the specification does not provide enablement for the specific release profiles recited in claims 27 and 28. The Office argues that the practitioner would have to turn to trial and error experimentation in order to prepare the claimed dosage form. Applicants respectfully traverse.

Applicants submit that the experimentation would not be undue. The art of formulating pharmaceuticals is advanced and well developed.

According to claim 27, tramadol and diclofenac are released in amounts of more than 70 % and more than 60 % by weight, respectively, within 16 hours. Claim 28 limits the time period for this release to 8 hours. As noted, the

specification provides examples 1-4 which exhibit the following release profile at 8 hours.

Example	Release fraction of Tramadol in % by weight*	Release fraction of Diclofenac in % by weight*
1	79	71
2	89	78
3	98	72
4	98	99

* see the tables on pages 11, 13, 15 and 16 of the specification and Figures 1-4.

These examples demonstrate to the skilled artisan just how to achieve release profiles commensurate with that recited in claims 27 and 28. Any experimentation required to achieve the claimed release profile with other formulations would not amount to undue experimentation, but instead would merely be routine experimentation in the art of pharmaceutical formulation. Indeed, the highly skilled artisan in the art of formulating pharmaceuticals would have no difficulty in adjusting the release parameters of a given formulation so as to achieve the requirements of these claims.

Reconsideration and withdrawal of this rejection are therefore respectfully requested.

The rejection of claims 1-9, 11-16, 20, 21, 24, and 26-28 under 35 U.S.C. § 103(a) over Voss et al. (U.S. Patent No. 4,690,927) in view of On (U.S. Patent

No. 6,319,514) is respectfully traversed. The rejection of claims 1-9, 11-16, 20, 21, 24 and 26-28 under 35 U.S.C. § 103(a) over Voss et al. in view of Raffa (EP 0 546 676 A1) is respectfully traversed. The rejection of claims 1-28 under 35 U.S.C. § 103(a) over Voss et al. in view of Raffa or On, and Oshlack *et al.* (U.S. Patent No. 6,077,533) is respectfully traversed.

The present invention relates to the discovery that tramadol (hydrochloride) and diclofenac (sodium) form a sparingly soluble compound. That is, when formulated together, these ingredients form a compound with a relatively low solubility. This low solubility is undesirable where there is a need to ensure that the active ingredients are released from the formulation within a short time following administration. By providing these active ingredients in separate subunits no such sparingly soluble compound is formed and the active ingredients may be release more quickly than if the active ingredients were simply mixed together.

Thus, providing the active ingredients in separate subunits provides an unexpected and unforeseen beneficial effect, namely that the release of the active ingredients can proceed much faster than if the ingredients were mixed together during the formulation process. In particular, in certain embodiments the invention allows the skilled artisan to achieve a release rate of tramadol (hydrochloride) and diclofenac (sodium) from a common administration unit which matches the release rate from administration units having only tramadol (hydrochloride) or diclofenac (sodium) as the active ingredient, see, e.g. paragraph [0048] of the present application and Figures 1, 3 and 4.

The deficiencies in the cited references, taken as cited by the Office, have been discussed previously. There is nothing in any of the cited art, as combined by the Office, which even hints at these unexpected benefits. Even if a showing of obviousness is believed to have been presented, it is overcome by the unexpected beneficial results achieved in accordance with the invention of the present claims. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

CONCLUSION

In view of the foregoing, the application is respectfully submitted to be in condition for allowance, and prompt favorable action thereon is earnestly solicited.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket No. 029310.50777CP).

Respectfully submitted,

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